

BEST AVAILABLE COPY

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
13 January 2005 (13.01.2005)

PCT

(10) International Publication Number
WO 2005/003149 A1

- (51) International Patent Classification⁷: **C07J 73/00**,
A61K 31/58
- (21) International Application Number:
PCT/GB2004/002906
- (22) International Filing Date: 5 July 2004 (05.07.2004)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
676/MUM/2003 3 July 2003 (03.07.2003) IN
- (71) Applicant (for all designated States except US): **CIPLA LIMITED** [IN/IN]; 289 Bellasis Road, Mumbai central, Mumbai 400 008 (IN).
- (71) Applicant (for MW only): **WAIN, Christopher, Paul** [GB/GB]; A A Thornton & Co, 235 High Holborn, London WC1V 7LE (GB).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): **KANKAN, Rajendra, Narayanrao** [IN/IN]; A-3/5, NBD Society, NSS Road, Ghalkopar (West), Mumbai 400 084, Maharashtra (IN). **RAO, Dharmaraj, Ramachandra** [IN/IN]; 4/403 Garden Enclave, Pokhran Road 2, Thane West, Mumbai 400 601, Maharashtra (IN).
- (74) Agents: **WAIN, Christopher, Paul et al.**; A A Thornton & Co, 235 High Holborn, London WC1V 7LE (GB).
- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).
- Published:
— with international search report
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: PROCESS FOR THE PREPARATION OF FINASTERIDE FORM I

(57) Abstract: A process of preparing finasteride Form (I), which process comprises dissolving finasteride in a solvent, replacing the solvent partially or substantially completely with a nonsolvent and thereafter isolating finasteride Form (I). There is also provided finasteride Form (I) prepared in accordance with the present invention, and the therapeutic use thereof in the inhibition of 5-alpha reductase, and pharmaceutical compositions containing the same.

WO 2005/003149 A1